

1 RECORD OF ORAL HEARING

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3 UNITED STATES PATENT AND TRADEMARK OFFICE

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6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES

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10 Ex parte ARTHUR A. GERTZMAN and
11 MOON HAE SUNWOO

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14 Appeal 2007-0532
15 Application 10/828,316
16 Technology Center 1600

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19 Oral Hearing Held: March 8, 2007

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23 Before TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK,
24 Administrative Patent Judges

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26 ON BEHALF OF THE APPELLANT:

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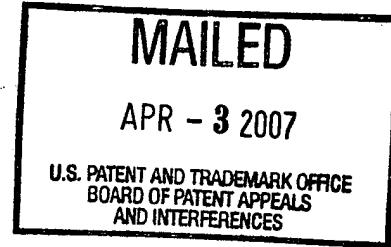
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35 The above-entitled matter came on for hearing on Thursday,
36 March 8, 2007, commencing at 1:06 p.m., at The U.S. Patent and Trademark
37 Office, 600 Dulany Street, Alexandria, Virginia, before Victoria L. Wilson,
 Notary Public.



1 THE CLERK: Good afternoon. Calendar number 9. Mr. Hale.

2 JUDGE SCHEINER: Thank you.

3 THE CLERK: You're welcome.

4 JUDGE SCHEINER: Good afternoon.

5 MR. HALE: Good afternoon. And it is after yesterday, right?

6 JUDGE SCHEINER: Yes.

7 Well, I don't know whether you have been in to see us since we
8 have a court reporter.

9 MR. HALE: No, I have not.

10 JUDGE SCHEINER: This is something new.

11 MR. HALE: This is the first time since that.

12 JUDGE SCHEINER: New for us, too, fairly new.

13 MR. HALE: Hopefully I'm not before you all that much, but I
14 don't know if that's good or bad.

15 JUDGE SCHEINER: One thing we did want to ask is if you
16 have a term that may have spelling that's not readily apparent, if you could
17 spell it into the record -- or I see you don't have -- or maybe the names of the
18 references. I don't know if you have references there.

19 MR. HALE: You have Doyle, Sander and Breithart as the
20 references?

21 JUDGE SCHEINER: Yes.

22 MR. HALE: Do you want me to spell those in?

23 JUDGE SCHEINER: Please. As they come up.

24 MR. HALE: What about the et al.s, or can I just refer to them
25 by the base name?

1 JUDGE SCHEINER: By the base name would be fine.

2 MR. HALE: Okay. Fine. Thank you.

3 JUDGE SCHEINER: And if there are any terms, scientific
4 terms or --

5 MR. HALE: No.

6 I would like to start out before the board to explain a little bit
7 about the invention and why it works and what the novelty and what the
8 scientific aspects of it are.

9 This is a formable material which is used by surgeons in
10 growing new bone in patients to cure bone defects, such as where there has
11 been a breakage, pieces have fallen out, where you are putting in new spine -
12 - into the spine; you may be putting in a fusing apparatus and you have to fill
13 the areas around it.

14 It is shaped by the surgeon at the time of surgery to fit the
15 particular hole, defect or area that it is going to go into. It contains
16 demineralized bone particles which promote the growth of bone. It is
17 osteoinductive. That means it causes new bone cells to grow rather than
18 simply house a matrix so that it can form additional solid material.

19 "Demineralized bone" is a term in the art that's been used for a
20 long time, and it was first brought by Marshall Urist, and it means a bone
21 which has been subjected to an acid to remove the mineral content, which is
22 somewhat akin to hydroxylapatite.

23 It is a calcium-based phosphate, so that the collagen fibers
24 which support the inner workings of the bone are exposed. The reason you
25 want them exposed is because the proteins on those fibers have little

1 receptors and growth factors which cause brand-new bone to grow.

2 So it causes, when you use demineralized bone, new bone to
3 grow in the place, which is, obviously, better than some kind of a synthetic
4 situation which is put in there.

5 The demineralized bone is characterized in the art as bone
6 which is demineralized so that less than 8 percent of the mineral remains in
7 the bone. So it is, basically, a small amount of mineral with a lot of collagen
8 fibers left after you have gone through this process.

9 And because it is an acidic process, no matter how much you
10 wash it, there is going to be an acid base to the product. So it is important
11 from a healing standpoint that you have the osmolality of the body neutral so
12 that you can immediately start to grow bone so that the healing process can
13 begin.

14 If it is acidic when it goes into the bone, it will require from
15 five to seven days for the body to actually change the pH to a period where it
16 can then start to do the natural healing processes.

17 I would emphasize that this is not a cement. This is not a block
18 of material.

19 Now, the examiner has cited three pieces of prior art which he
20 has combined to argue that it is obvious, that the invention is obvious.

21 He cited Doyle, D-O-Y-L-E, which is a shaped solid block of
22 material. It is hard and chalk-like and is made from compressing elongated
23 bone fibers into a solid mass. If you can think of it as basically a brick that
24 the surgeon then whittles away to use however they want to in replacement.

25 JUDGE GRIMES: I think the reference here you are referring

1 to is actually Boyce, B-O-Y-C-E.

2 MR. HALE: You are right. You are right. I have a problem
3 with my own handwriting, which is not unusual. Thank you.

4 The second reference is Sander, S-A-N-D-E-R, et al., which is a
5 bone cement. It is a polymethyl-methyl acrylic and it does not have
6 demineralized bone in it. It is basically a synthetic polymer. The third
7 reference is Breithart, B-R-E-I-T-H-A-R-T, et al., which is a synthetic
8 polymer matrix having a sponge-like consistency.

9 All three of these end up being rather hard masses, unlike the
10 present invention, which is a formable softer mass, which is, in fact, washed
11 away by body fluids after it is in place about a month, but by that time,
12 indeed, after a few days, the growth process of the bone has already started
13 so that the new cellular growth has already been accentuated.

14 The prior art does not show the particle size of demineralized
15 bone, which is claimed in the dependent claims; it is not claimed in the
16 independent claims. Prior art does not show the percentage demineralized
17 bone which is needed. Here we claim 20 to 35 percent.

18 The reason that this is important, because when it goes over 50
19 percent, it is no longer malleable or formable; it falls apart in little pieces
20 and you can't use it.

21 The surgeon would essentially try and make the little blob that
22 he sticks into the hole and it would fall apart in his hands, so it couldn't be
23 used. So the percentage of demineralized bone is important in this particular
24 composition.

25 JUDGE GRIMES: But that's not in the independent claim

1 either, is it?

2 MR. HALE: No. Those are both in the dependent claims.

3 JUDGE GRIMES: Well, let's start with the independent claim.

4 That's 21 and 23.

5 MR. HALE: Sure.

6 JUDGE GRIMES: And I would be interested in comparing
7 those -- the components of those claims with what's in Boyce in making the
8 composition that they are going to then harden up into the hard --

9 MR. HALE: Well, Boyce uses a heat treatment and a
10 compression treatment to form a hard block of elongated particles.

11 JUDGE GRIMES: Correct.

12 MR. HALE: Those particles --

13 JUDGE GRIMES: Before they are heated or compressed,
14 though, isn't the -- isn't the composition characterized as a slurry or a paste?

15 MR. HALE: Yes, that is true, but it is not applied to the patient
16 at the site at that time; it is done in the manufacturing to arrive at the
17 composition.

18 JUDGE GRIMES: But you are claiming a composition. You
19 are not claiming a method that includes putting that formable paste into the
20 patient.

21 MR. HALE: But there is also -- it is not viscous, obviously,
22 and it is not applied -- at that stage, it is not used. It is not used for any
23 medical aspect whatsoever.

24 JUDGE GRIMES: Yet, it is the composition that you are
25 claiming, and so if the composition was known in the art even for a different

1 purpose, then that would read on your -- your claim --

2 MR. HALE: I would respectfully disagree with you on that
3 because it is a method of making a composition, and in the method, they do
4 put a -- I will agree with you in the characterization that it is a slurry.

5 However, there is no viscosity once the item of utility has been
6 made. The item of utility is a chalk rock-like material which is carved or
7 formed into a hard load-bearing particular object. It cannot be molded by
8 the surgeon. You could not utilize that material in the premanufacturing
9 state, which is, I assume, what we are talking about now. Correct, sir?

10 JUDGE GRIMES: Correct.

11 MR. HALE: Yes. As a medical item.

12 JUDGE GRIMES: But that's not part of your claim. Your
13 claim is to a composition that has certain compounds, certain elements in it.
14 It doesn't say that --

15 MR. HALE: Okay.

16 JUDGE GRIMES: It doesn't say --

17 MR. HALE: There is no hydrogel that is used in that, such as
18 chitosan or sodium alginate. There is no percentage that is stated.

19 JUDGE GRIMES: The examiner --

20 MR. HALE: There is no -- excuse me a second. Can I just
21 finish this and then -- then you can cut me to shreds, okay? There is no pH
22 stated, which is necessary, and there is no growth factor or, in the other
23 independent claim, cells.

24 JUDGE GRIMES: All right. Let's take those in order.

25 Chitosan, the examiner pointed to the disclosure of chitosan there, I believe.

1 MR. HALE: That's an adhesive in a laundry list of about 30
2 different possibilities that can be used to fasten the particles together during
3 the compression process.

4 JUDGE GRIMES: So it is an optional component as a binder.

5 MR. HALE: As a binder. Yes, that is stated in there.

6 JUDGE GRIMES: And there is a whole list of bioactive
7 substances that can be in there, which include living cells. This is column 9,
8 about lines 45 to 50. Autogenous tissues, like blood or serum, that's about
9 line 52; TGF beta, that's line 59; those are growth factors as required by
10 claim 21 or cells as required by claim 23. Okay.

11 MR. HALE: Well, if you are going to do that, then you can't --
12 then you can't allow them to put holes in it after it's been manufactured to
13 add it to it.

14 So it seems to me that that is an argument that takes one part,
15 the manufacturing step, then ignores the manufacturing step and goes to the
16 manufactured item, which is then made porous to hold those things. So it
17 seems to me it's got to be either one way or the other way.

18 JUDGE GRIMES: The reference says you combine the bone
19 particles with the wetting agent and all this other stuff to make your slurry.
20 This is column 10, about lines 20 to 30. Method of fabricating the bone
21 particle containing composition involves wetting a quantity of bone
22 particles.

23 Optionally, the wetting agent can comprise dissolved or add
24 mix therein biocompatible substances such as binders, fillers, bioactive
25 substances, et cetera.

1 MR. HALE: All right. I would also direct you to the fact that
2 once this is made, it is heated, which would kill all of those cells, all of those
3 growth factors.

4 JUDGE GRIMES: Be that as it may, they still suggest making
5 a composition that comprises all those things in a slurry or paste.

6 MR. HALE: They may suggest, but they do not teach. They
7 do not teach the purpose. They do not teach the amounts. They do not teach
8 the effect that will be desired. There must be a rational reason for
9 combining the references to arrive at the invention rather than looking at the
10 invention and going backward with hindsight, which I submit is what was
11 done by the examiner.

12 JUDGE GRIMES: Well, they suggest making it. They
13 expressly suggest making that slurry or paste composition comprising bone
14 particles, demineralized bone and chitin and bioactive substances. It is an
15 express suggestion. How much more clear can it get?

16 MR. HALE: Well, they don't then suggest using the slurry by
17 itself for doing anything. They use the slurry then to heat, compress and
18 make into a block-like form. And by the very nature of the heating, that will
19 destroy the growth factors and it's going to destroy the cells.

20 So why it is in there, I don't know, other than it is a laundry list
21 of everything that he could think of he put in the particular patent. But I
22 don't believe it is a teaching. It would be contrary if you applied it all the
23 way up and down the line.

24 I don't think there is anything in there that says that that slurry
25 is to be used in any kind of a medical treatment or has any use other than the

1 fact that it is the base for that block, which is then compressed and heated. I
2 see no suggestion that says anywhere in the patent that the slurry by itself is
3 to be used for any medical usage.

4 JUDGE GRIMES: Okay. Then I have already made the point
5 that your claim is to a composition, not a method --

6 MR. HALE: I'm sorry. I could not hear you.

7 JUDGE GRIMES: But I have already made the point that your
8 claims are to a composition, not a method of putting something specific into
9 a particular patient.

10 MR. HALE: I understand your point.

11 JUDGE GRIMES: I'm not saying I agree with you that that
12 distinction makes a difference.

13 MR. HALE: I do realize your point. I would respectfully
14 disagree with your point. I do not believe, as I have said, and certainly I
15 don't -- we have a difference of opinion. We are looking at it from different
16 ways.

17 But I do not believe that the composition that you have taken
18 has been shown to be useful in the arts or that it would be useful in the arts
19 or that it was intended to be used in the arts and that it is only used in a
20 process for then changing it to something else which is totally different.

21 That would be my argument.

22 As I said, there is no viscosity. There is, if we take the -- your
23 original slurry thing, of course, it is going to -- it is going to probably have a
24 viscosity, though that viscosity is unknown. It is going to have a pH, but
25 that pH is unknown.

1 And it is going to be acidic because of the very nature of the use
2 of demineralized bone particles in the slurry. It is highly acidic, so it is not
3 going to have a neutral pH, the slurry will not. There is no weight of the
4 hydrogel that's used.

5 And the bone concentration is above 50 percent. Plus, it is
6 elongated bone which could not be used to form a malleable defect area
7 because it would just be -- it just simply would not work. It's got a bone
8 composition and a bone size which does not allow it to be molded by hand
9 by a physician.

10 The amount of cells required is not shown. It just says, Add
11 some cells. Now, you have got to understand that you are in a body where
12 there is going to be a washing of blood and fluids, and that if you don't know
13 a cell range to fall into, you are either going to put too few in, which are
14 going to be washed away and which are going to take away from what you
15 want to accomplish.

16 I mentioned the fact there is no neutral pH and that the carriers
17 are not set forth, other than the fact as a thickener and in no amount.

18 Are there any other questions that the board has?

19 JUDGE GRIMES: With respect to the pH limitation, I'm
20 looking at the examples in the specification and I'm not seeing any particular
21 treatment required to achieve that.

22 MR. HALE: To achieve what, Judge?

23 JUDGE GRIMES: To achieve the neutral pH. You are saying
24 that demineralized bone is normally acidic.

1 MR. HALE: Yes. It is made from hydrochloric acid is the way
2 it is done, and they basically drop it in hydrochloric acid and bubble away all
3 the elements.

4 JUDGE GRIMES: Then they wash away the residual acid, do
5 they not?

6 MR. HALE: Not -- yes and no. Yes, they wash away the
7 residual acid, but there still is -- it still is acidic in pH. It does not have the
8 acid on it but it still is -- if you take the bone pH by itself, it is acidic.

9 JUDGE GRIMES: Okay. So I guess when the specification
10 says that the pH is supposed to be in the range of 6.8 to 7.4, you are saying
11 that those skilled in the art would realize you have to pretreat the
12 demineralized bone in some way to achieve that?

13 MR. HALE: I'm saying that that is -- that is the range that a
14 human body runs. That's what -- that's what the figures are. That's -- the pH
15 range that --

16 JUDGE GRIMES: What I am trying to get at --

17 MR. HALE: -- that the human body has.

18 JUDGE GRIMES: What I am trying to get at is, there is no
19 disclosure in the spec of any particular treatment required to achieve this
20 level of pH, and so I'm wondering if the lack of disclosure in the reference
21 about a pH is really that significant.

22 MR. HALE: Well, they -- it discloses using a phosphate buffer
23 aqueous solution which brings the pH down. So that is part of the claims.
24 And that is added into the composition which is a necessity to bring that
25 down. So I think there is a teaching.

1 Any of other judges have any comments or questions? Not to
2 exclude you, Judge Grimes.

3 JUDGE SCHEINER: I don't have any.

4 Do you have anything further?

5 JUDGE GRIMES: No.

6 JUDGE SCHEINER: Thank you for coming in.

7 MR. HALE: I have no further material to present. I don't want
8 to read the brief. I think that takes the board's time up for something that's
9 totally useless. The arguments are set forth what they are in that.

10 JUDGE SCHEINER: Okay. We understand the issues. Thank
11 you for coming in.

12 MR. HALE: Thank you.

13 JUDGE SCHEINER: Thank you for coming in.

14 MR. HALE: Okay. Thank you.

15 I would like to say that while I do get before the board several
16 times a year, which is quite enough for me, this has been my smoothest trip,
17 so I don't know what you have done to work out the problems, but there has
18 always been mess-ups before and this was very smooth.

19 Either downstairs that they don't know you are on the list or --
20 or they can't handle -- or you come up here, but this just (snapping).

21 JUDGE SCHEINER: That's nice to hear.

22 MR. HALE: This was very good. There is one problem,
23 though. I will tell you that. That is, will I remember from here to
24 downstairs to pick up my driver's license?

25 Thank you all.

1 JUDGE SCHEINER: Thank you.

2 Whereupon, the proceedings at 1:26 p.m. were concluded.